UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF GEORGIA COLUMBUS DIVISION

IN RE: MENTOR CORP. OBTAPE TRANSOBTURATOR SLING PRODUCTS LIABILITY LITIGATION

MDL CASE NO. 4:08MD2004

JUDGE CLAY D. LAND

TERESA TAYLOR,

Plaintiff,

vs.

MENTOR CORPORATION and MENTOR WORLDWIDE, LLC,

Defendants.

CIVIL ACTION NO. 4-12-cv-176 (CDL)

COMPLAINT

Plaintiff, TERESA TAYLOR, ("Plaintiff') sues the Defendants, MENTOR CORPORATION ("MENTOR") and MENTOR WORLDWIDE, LLC ("MENTOR LLC") collectively referred to as ("Defendants") and alleges as follows:

1. This action is being direct filed as a potential tag-along case to the multi-district litigation proceedings currently pending before the court, IN RE: MENTOR CORP. OBTAPE TRANSOBTURATOR SLING PRODUCTS LIABILITY LITIGATION, MDL 2004, Case No. 4:08-MD-02004 CDL.

2. This action is being direct filed in the Middle District of Georgia pursuant to Judge Land's December 12, 2011 Order authorizing direct filing [DE 446].

3. Plaintiff, TERESA TAYLOR, is seeking damages in excess of $75,000.00, exclusive of interest and costs.

4. Defendant MENTOR is a Minnesota Corporation with its principal place of business located in the State of California.

5. Defendant MENTOR LLC is a Delaware Corporation with its principal place of business in Santa Barbara, California.

6. It is believed that MENTOR LLC has assumed the assets, rights and obligations of MENTOR and as such is responsible to the Plaintiff for damages if any awarded.

7. At all times material hereto, MENTOR conducted business within the State of Minnesota, including maintenance of a sales force within the State of Minnesota and manufactured, tested, analyzed, distributed, labeled, sold, supplied, marketed and/or promoted a transobturator vaginal sling product known as "ObTape" and placed said medical device into the stream of commerce.

8. MENTOR began to first market ObTape brand transobturator vaginal sling in the United States in 2003.

9. Upon information and belief, at the time that MENTOR first introduced its ObTape brand transobturator vaginal sling to the market in 2003, the product had undergone inadequate pre-market testing to determine the safety and efficacy of the medical device prior to implantation in humans, and said testing was limited to animal testing (and included only three rabbits).

10. However, even the limited animal testing conducted by MENTOR prior to first marketing the ObTape brand transobturator vaginal sling in 2003 had demonstrated that the medical device caused adverse tissue reactions in the rabbits.

11. Further, upon information and belief, MENTOR knowingly and deliberately made material misrepresentations to the Food & Drug Administration concerning the safety, efficacy, design and manufacture of its ObTape brand transobturator vaginal sling.

12. After 2003, upon information and belief, MENTOR performed no additional safety or efficacy testing in human vaginal tissues to confirm that the medical device was safe and effective for use in women.

13. From 2003 through March of 2006, MENTOR continued to manufacture, market, distribute, and sell this device to thousands of women even though MENTOR knew that the product had been inadequately tested for safety and efficacy (both prior to and after its approval for sale in the United States), contained significant manufacturing and design defects that posed unnecessary risks to patients, and also despite knowing that numerous patients had suffered harm attributable to the defective condition of the medical device and the negligence of MENTOR.

14. Prior to Plaintiff's implantation with this device, MENTOR was on notice of numerous patients who had been harmed by its ObTape brand transobturator vaginal sling, including a significant number of women who suffered vaginal erosion, infection, extrusion, perforation and/or abscess after implantation with its device.

15. MENTOR did not cease to manufacture, market, distribute, and sell its ObTape brand transobturator vaginal sling until approximately March of 2006, and even after its withdrawal of the medical device from the market due to safety issues, MENTOR failed to provide adequate warnings and notice to physicians and/or patients regarding the unacceptably high rate of vaginal ObTape brand transobturator vaginal sling and the best methods for treating patients who were previously implanted with the defective devices, including Plaintiff.

16. This failure to provide adequate warnings and information to physicians and/or patients following withdrawal of the medical device from the market in March of 2006 led to unnecessary suffering and delay in obtaining appropriate medical treatment for Plaintiff as well as the thousands of other women who were implanted with the defective medical device.

17. On or about March 18, 2004, Plaintiff was implanted with an ObTape brand transobturator vaginal sling designed, manufactured, packaged, labeled and sold by MENTOR. The subject sling was intended to treat Plaintiff for SUI, the use for which MENTOR marketed the product.

18. Plaintiff's treating physician implanted the subject sling properly and appropriately.

19. Subsequent to this implantation surgery, and as a direct and proximate result of the defective condition of MENTOR's ObTape brand transobturator vaginal sling, Plaintiff suffered serious and permanent bodily injuries, including erosion of the ObTape medical device, chronic infections, pain, exacerbation of her urinary incontinence, and the need for multiple additional surgical procedures and medical treatment as well as the need for extensive future medical care.

COUNT I – STRICT LIABILITY

20. Plaintiff adopts the allegations contained in Paragraphs 1 through 19 above as though fully set forth herein.

21. This is an action for design and manufacturing defect as well as lack of an appropriate and necessary warning. Defendants are strictly liable to Plaintiff for designing, manufacturing, marketing and/or selling a defective product.

22. MENTOR's ObTape brand transobturator vaginal sling device was expected to, and did in fact, reach Plaintiff without a substantial change in its condition from the time of the device's manufacture.

23. Plaintiff used MENTOR's ObTape brand transobturator vaginal sling device for its intended purposes, and the ObTape brand transobturator vaginal sling device was not materially altered or modified prior to its use.

24. The ObTape brand transobturator vaginal sling device implanted in Plaintiff and manufactured, sold, distributed and marketed by MENTOR was defective and unreasonably dangerous when it left the possession of MENTOR in the following manner:

a. When placed into the stream of commerce, MENTOR's ObTape brand transobturator vaginal sling device contained unreasonably dangerous manufacturing and design defects, such that it posed an unreasonable risk of harm to Plaintiff;

b. When placed into the stream of commerce, MENTOR's ObTape brand transobturator vaginal sling device deviated materially from MENTOR's design and manufacturing specifications for this particular medical device in such a manner as to pose an unreasonable risk of harm to Plaintiff;

c. When placed into the stream of commerce, the risks associated with MENTOR's ObTape brand transobturator vaginal sling device exceeded the benefits associated with its use;

d. MENTOR's ObTape brand transobturator vaginal sling device failed to perform as an ordinary consumer would expect when used as intended or in a manner reasonably foreseeable by MENTOR;

e. MENTOR failed to properly manufacture the device implanted in Plaintiff with a minimum pore size of 50 microns or greater (as is necessary to ensure proper tissue in-growth following implantation), but, instead, manufactured its ObTape brand transobturator vaginal sling devices with a smaller pore size, which impaired proper tissue in-growth and resulted in an increased risk of infection, abscess formation, vaginal erosion, extrusion and other serious harm to Plaintiff and others;

f. The material utilized by MENTOR for the construction of its ObTape brand transobturator vaginal sling device (i.e., non-woven, microporous, inelastic polypropylene mesh) was inappropriate for use in a patient's vagina.

g. The pore size of the polypropylene mesh material selected by MENTOR for use in its ObTape brand transobturator vaginal sling device was insufficient to allow for proper physiological reaction of the body to the device, including proper in-growth of tissue and vessels;

h. The inappropriate material and inadequate pore size in the materials selected by MENTOR for use in its ObTape brand transobturator vaginal sling device created a propensity for that device to cause infections and/or the formation of abscesses when placed in the vaginal area, which, in turn, resulted in an unreasonably high rate of infections, abscesses, erosion, perforation, and extrusion in Plaintiff and others;

i. The ObTape brand transobturator vaginal sling devices contained a lack of warnings or inadequate warnings to alert Plaintiff, Plaintiff's physicians, and others of severe and life threatening complications and risks associated with use of the product including vaginal erosion, infection, extrusion, perforation and/or abscess;

j. The foreseeable risks of harm posed by the design of the ObTape brand transobturator vaginal sling device could have been reduced and/or avoided by MENTOR if it had adopted a reasonable alternative design, and MENTOR's failure to adopt a safer alternative design rendered its ObTape brand transobturator vaginal sling device unreasonably dangerous;

k. The ObTape brand transobturator vaginal sling devices were insufficiently tested and/or inspected, both before and after being placed on the market in 2003; and

l. There were insufficient warnings (both before and after the product's implantation in Plaintiff and during the roughly three years that the product was manufactured, marketed and sold) to alert Plaintiff, Plaintiff's physicians, and others of severe and life threatening complications and risks associated with use of the product, the high rate of failures associated with this particular product, that this device was more likely than other competing products to pose harm to patients, that the product should be removed in its entirety (rather than piecemeal or not at all) when potential problems are noted, and other information critical to the safety and well-being of Plaintiff and others, at a time long after MENTOR knew or should have known of these significant risks and safety issues associated with the product.

25. MENTOR, as a manufacturer of medical devices, is held to the level of knowledge of experts in the field.

26. Plaintiff's physicians did not have substantially the same knowledge as MENTOR or the knowledge that would have been gleaned from an adequate warning from the manufacturers.

27. MENTOR had a continuing duty to warn the Plaintiff, Plaintiff's physicians, and others of the dangerous risks associated with use of its ObTape brand transobturator vaginal sling devices and proper management of patients who have been implanted with this device, and failed to do so.

28. Plaintiff and Plaintiff's physicians did not and could not have known at the time of her surgery in March of 2004, or any time prior, of the existence of the defective and unreasonably dangerous condition of MENTOR's ObTape brand transobturator vaginal sling devices.

29. As a direct and proximate result of the defective condition of the ObTape brand transobturator vaginal sling device, Plaintiff has suffered and continues to suffer from serious injuries, including, but not limited to, pain and suffering; permanent physical injuries; disability; significant disfigurement; embarrassment and mental anguish; loss of capacity for the enjoyment of life; expenses of hospitalization; surgical; medical and nursing care treatment; aggravation of a previously-existing condition; loss of earnings; loss of the ability to earn money in the future; and a shortened life span. These losses are either permanent or continuing.

WHEREFORE, Plaintiff demands judgment against Defendants for damages, as well as costs of this action, and a trial by jury of all issues to be tried.

COUNT II – NEGLIGENCE

30. Plaintiff adopts by reference all of the allegations contained in Paragraphs 1 through 29 above, each inclusive, as though fully set forth herein.

31. At all times material hereto, MENTOR had a duty to Plaintiff to exercise reasonable care in the design, manufacture, testing, inspection, sterilization, processing, advertising, marketing, testing, labeling, assembling, packaging, distribution, warning, detailing, promotion and sale of its ObTape brand transobturator vaginal sling devices.

32. In addition, MENTOR had an obligation to issue a timely post-sale warning regarding risks that became known after it either first began marketing its product and/or after Plaintiff began using MENTOR's product.

33. At all times material, MENTOR failed to exercise reasonable care under the circumstances, as it knew, or in the exercise of reasonable care, should have known, that its ObTape brand transobturator vaginal sling devices were not properly manufactured, compounded, assembled, inspected, packaged, distributed, tested, analyzed, examined, or prepared, such that the medical devices were likely to injure its users, including Plaintiff herein.

34. Also, MENTOR failed to exercise reasonable care under the circumstances, as it knew, or in the exercise of reasonable care, should have known, that its ObTape brand transobturator vaginal sling devices were sold without sufficient warnings or instruction (both before as well as after their sale), such that the medical devices were likely to injure its users, including Plaintiff herein.

35. Further, MENTOR failed to exercise reasonable care under the circumstances, as it knew, or in the exercise of reasonable care, should have known, that its ObTape brand transobturator vaginal sling devices and the information (including warnings, instructions, detailing, advertising, promotion, and representation) about the characteristics and properties of the devices; the potential risks associated with their use in patients; safety and efficacy data; the attributes of these devices relative to other competing medical devices; and the management of

patients after implantation of these devices were inaccurate or incomplete, such that the medical devices were likely to injure its users, including Plaintiff herein.

36. MENTOR also failed to conduct sufficient testing and/or inspection of its ObTape brand transobturator vaginal sling devices, both prior to and after approval of the product for sale in 2003, which, if properly performed, would have revealed or led, long ago, to the detection of defects in the products and inadequacy in the warnings and instructions which accompanied the devices, such that the injuries suffered by Plaintiff herein could have been prevented.

37. These negligent acts by MENTOR resulted in the sale of medical devices that were dangerous, unsafe, and not reasonably fit for the uses and purposes for which the medical devices were intended, including the particular ObTape brand transobturator vaginal sling device implanted in Plaintiff.

38. MENTOR knew or should have know that the ObTape brand transobturator vaginal sling devices subjected Plaintiff to unreasonably dangerous risks of which the Plaintiff and her treating physicians would not be aware. Nevertheless, MENTOR advertised, marketed, sold and distributed the ObTape brand transobturator vaginal sling devices for years to thousands of women, at a time when MENTOR knew that there were safer methods and products available for the treatment of urinary incontinence.

39. As a direct and proximate result of the negligence of MENTOR, Plaintiff has suffered and continues to suffer from serious injuries, including, but not limited to, pain and suffering; permanent physical injuries; disability; significant disfigurement; embarrassment and mental anguish; loss of capacity for the enjoyment of life; expenses of hospitalization; surgical, medical and nursing care treatment; aggravation of a previously-existing condition; loss of

earnings; loss of the ability to earn money in the future; and a shortened life span. These losses are either permanent or continuing.

WHEREFORE, Plaintiff, TERESA TAYLOR, demands judgment against MENTOR for damages, as well as costs of this action, and a trial by jury of all issues to be tried.

JURY TRIAL DEMANDED ON ALL ISSUES

Dated this 12th day of July, 2012.

Respectfully submitted,

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